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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,361	03/18/2005	Dan Peters	2815-0207PUS2	5012

2292 7590 09/28/2006

BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/528,361

Applicant(s)

PETERS ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,7,9,23,24,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,23,24,34 and 35 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 2, 7, 9, 23, 24, 34 and 35 are pending in the application.

This action is in response to applicants' amendment dated July 13, 2006. Claims 1, 2, 7, 9 and 24 have been amended, claims 3-6, 8, 10-22 and 25-32 has been canceled and claims 34 and 35 are newly added.

### ***Response to Arguments***

Applicant's arguments filed July 13, 2006 have been fully considered with the following effect:

1. The applicants' amendment to the first line of the specification which states that "This application is the National Phase of PCT International application No.PCT/DK2003/000639 filed on September 29, 2003, which claims priority under 35 U.S.C. 119(e) to U.S. Provisional Application No(s). 60/426,368 filed on November 15, 2002 and under 35 U.S.C. 119(a) to Patent Application No(s). PA 2002 01456 & PA 2002 01738 filed in Denmark on September 30, 2002 & November 11, 2002, respectively."

However, as stated in the last office action, the reference to the applicants' priority documents in the first line of the specification is limited to those applications filed under 35 U.S.C. § 119(e) and/or 35 U.S.C. § 120, 121 or 365(c) not 35 U.S.C. § 119(a) as appears in the amendment to the specification.

2. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) in the last office action, the applicants' stated that claims 25-32 have been canceled and that claims 23 and 24 have been amended in a manner consistent with the relevant

points made by the Examiner. However, claim 24 provides for the prevention of disease or disorder associated with withdrawal symptoms caused by termination of use of tobacco, heroin, cocaine, morphine, benzodiazepines, benzodiazepine-like drugs or alcohol. Instant claim language embraces disorders not only for treatment but also for **prevention**, which is not remotely enabled. It is presumed in the prevention of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop a disease or disorder associated with withdrawal symptoms caused by termination of use of tobacco, heroin, cocaine, etc. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the diseases and/or disorders claimed herein.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record.

3. The applicants' amendments are arguments sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled 4) of the last office action, which are hereby **withdrawn**.

4. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled 5) of the last office action, which is hereby **withdrawn**.

5. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled 6) of the last office action, which is hereby **withdrawn**.

In view of the amendment dated July 13, 2006, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1, 2, 7, 23, 24, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claims 1, 2, 7, 23, 24, 34 and 35 are vague and indefinite in that it is not known what is meant by the definition of the variables n and X where there are no variables n and X in formula (IV).

b) Claims 34 and 35 are vague and indefinite in that it is not known what is meant by "derivative" which implies more than what is positively recited.

"Compound" is suggested.

***Claim Objections***

7. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brenda L. Coleman

Primary Examiner Art Unit 1624

September 21, 2006